

REMARKS/ARGUMENTS

The present application has been reviewed in light of the Final Office Action mailed October 25, 2004. Claims 16-19, 22-33 and 36-44 are pending in the application, claims 16, 30 and 44 having been amended herein. Reconsideration of the present application, as amended, is respectfully requested.

In view of the Examiner's earlier restriction requirement, Applicant reserves the right to present previously withdrawn claims 1-15 and 45-50 in a divisional application.

The amendment filed August 18, 2004, has been objected to under 35 U.S.C. §132 for introducing new matter into the disclosure, in particular, the material added at the end of the paragraph beginning at page 6, line 14 of the specification as well as the material in figure 1 of the drawings.

It is respectfully submitted that support for the material added to the specification, pursuant to the amendment filed August 18, 2004, can be found on page 6, lines 26-28, and in originally filed claims 23 and 37. In establishing a disclosure, applicant may rely not only on the specification and drawing as filed but also on the original claims if their content justifies. (see MPEP 608.04). While a question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)), there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Consequently, rejection of an original claim for lack of written description should be rare. (see MPEP 2163.03). Additionally, the claims as filed in the original specification are part of the disclosure and therefore, if an application as originally filed contains

a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985).

The specification as originally filed, recites at page 6, lines 26-28, *inter alia*, that the radially expandable sleeve can have a plastic or other **locking structure** so that, once expanded, it will retain its large diameter configuration without the need for using other supports, devices, or the like. Originally filed claim 23 recites that the radially expandable sleeve is plastically deformable or has a **locking structure** so that it retains its expanded condition. Originally filed claim 37 recites that the radially expandable sleeve is plastically deformable or has a **locking structure** so that it retains its larger diameter after the dilator is withdrawn from the lumen of the sleeve.

Accordingly, in view of the remarks provided above, it is respectfully submitted that the objection of the disclosure under 35 U.S.C. §132 should be withdrawn.

The drawings have once again been objected to, under 37 C.F.R. 1.83(a), for failing to show every feature of the invention specified in the claims, namely the locking structure defined in claims 23 and 37. By the amendment filed August 18, 2004, FIG. 1 was amended to illustrate an exemplary locking structure. In particular, FIG. 1 was amended to show a locking structure in the form of a tether 15 which is fixedly secured to the distal end of radially expandable sleeve 12 and extends axially through sleeve 12, as recited by the specification as amended. In support thereof, a replacement sheet of figures, including the change to FIG. 1 to shown the exemplary locking structure, was submitted with the amendment of August 18, 2004. Accordingly, in view of submission of the replacement sheet of figures, submitted with the amendment of August 18,

2004, it is respectfully submitted that the objection of the drawings under 37 C.F.R. 1.83(a) should be withdrawn.

Claim 22 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendment to claim 16 herein, it is respectfully submitted that the rejection of claim 22 under 35 U.S.C. §112, second paragraph, has been overcome.

Claims 16-19 and 22-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horzewski et al. (U.S. Patent 5,201,756) in view of Makower et al. (U.S. Patent 5,380,290). It is respectfully submitted that claims 16-19 and 22-29, as amended herein, are allowable over Horzewski et al. in view of Makower et al.

It is respectfully submitted that Horzewski et al. taken alone or in proper combination with Makower et al. fails to teach or suggest amended independent claim 16.

Independent claim 16 presently recites a method for establishing vascular access, including the steps of, *inter alia*, positioning a radially expandable sleeve over the guidewire and through the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue tract, wherein the expandable sleeve is in a narrow diameter configuration, ***introducing a dilator over the guidewire***, and inserting the dilator into the radially expandable sleeve to radially expand the expansible sleeve to a larger configuration to provide an access lumen to the blood vessel.

Horzewski et al. discloses a sheath assembly consisting of a side arm sheath 90 and one or more dilators 150, 160. (see col. 11, lines 58-60). Typically, the sheath is prepared with the dilator 150 illustrated in FIG. 6B and this assembly is introduced over a guidewire within the confines of the vasculature. (see col. 12. lines 37-40) The sheath and dilator are designed such

that the distal end of the sheath is proximal to the bulbous region 127 of said dilator. (see col. 12, lines 56-59).

Makower et al. discloses that the distal end of the dilator is inserted into the proximal end of the catheter or introducer sheath, and advanced so that the part of the dilator, having the small slit, can be seen protruding beyond the distal end of the introducer sheath. (see col. 9, lines 54-58). In use the sharp tip of the needle/dilator is inserted so that the tip of the needle and the tip of the dilator are simultaneously in the vessel. (see col. 10, lines 32-34). Next, the guidewire-stop is removed and discarded and the guidewire is advanced through the needle/dilator and then some distance into the vessel. (see col. 10, lines 48-50).

It is respectfully submitted that Horzewski et al., taken alone or in any proper combination with Makower et al., fails to disclose, *inter alia*, positioning a radially expandable sleeve over the guidewire and through the tissue tract, and then inserting the dilator into the radially expandable sleeve to radially expand the expansible sleeve to a larger configuration to provide an access lumen to the blood vessel, as called for in claim 1.

It is therefore respectfully submitted that, in view of the amendments made to claim 16 herein, and in view of the arguments presented above, that claim 16 is allowable over Horzewski et al. in view of Makower et al.

Since claims 17-19 and 22-29 depend, directly or indirectly from claim 16 and contain all of the features of claim 16, for the reasons presented above regarding the patentability of claim 16, it is respectfully submitted that claims 17-19 and 22-29 are also patentable over Horzewski et al. in view of Makower et al.

Claims 30-33 and 36-44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horzewski et al. in view of Makower et al. as applied to claims 16-19 and 22-29 above, and

further in view of Dubrul et al. (U.S. Patent 5,431,676). It is respectfully submitted that claims 30-33 and 36-44, as amended herein, are allowable over Horzewski et al. in view of Makower et al. and in view of Dubrul et al.

It is respectfully submitted that Horzewski et al. taken alone or in proper combination with Makower et al. and/or Dubrul et al. fails to teach or suggest independent claim 30 and amended independent claim 44.

Independent claim 30 recites a method for establishing vascular access, including the steps of, *inter alia*, positioning a radially expandable sleeve over the guidewire and through the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue tract, wherein the expandable sleeve is in a narrow diameter configuration; ***introducing a dilator over the guidewire and through the expandable sleeve to increase the diameter of the expandable sleeve to a larger diameter***; and removing the dilator wherein the expandable sleeve retains the larger diameter.

As discussed above, neither Horzewski et al. nor Makower et al. disclose introducing a dilator over the guidewire and through the expandable sleeve to increase the diameter of the expandable sleeve to a larger diameter, as called for in claim 30. Accordingly, for the reasons presented above regarding the patentability of claim 16 over Horzewski et al. and/or Makower et al., claim 30 is also allowable over Horzewski et al. and/or Makower et al.

The examiner relies on Dubrul et al. solely for the proposition of providing an expandable sleeve constructed as a tubular braid. However, Dubrul et al. fails to remedy the deficiencies of Horzewski et al. and/or Makower et al. in that Dubrul et al. fails to teach or disclose introducing a dilator over the guidewire and through the expandable sleeve to increase the diameter of the expandable sleeve to a larger diameter, as called for in claim 30.

It is therefore respectfully submitted that, in view of the arguments presented above, that claim 16 is allowable over Horzewski et al. and/or Makower et al. in view of Dubrul et al.

Since claims 31-33 and 36-43 depend, directly or indirectly from claim 30 and contain all of the features of claim 30, for the reasons presented above regarding the patentability of claim 30, it is respectfully submitted that claims 31-33 and 36-43 are also patentable over Horzewski et al. and/or Makower et al. in view of Dubrul et al.

Independent claim 44 presently recites an improved method for establishing vascular access comprising, *inter alia*, introducing a radially expandable sleeve over the guidewire *prior* to introducing the dilator, and *thereafter* introducing the dilator over the guidewire through the sleeve.

As discussed above with regard to the patentability of claim 30, it is respectfully submitted that Horzewski et al. and/or Makower et al. in view of Dubrul et al. fail to disclose introducing a radially expandable sleeve over the guidewire prior to introducing the dilator, and thereafter introducing the dilator over the guidewire through the sleeve, as presently recited in claim 44.

Accordingly, in view of the amendments to claim 44 and in view of the arguments presented above, it is respectfully submitted that claim 44 is allowable over Horzewski et al., Makower et al. and Dubrul et al., taken alone or in any proper combination with one another.

In view of the amendments made to the claims herein, and in view of the remarks/arguments presented above, it is respectfully submitted that each of the objections and rejections raised by the examiner in the present Office Action have been overcome.

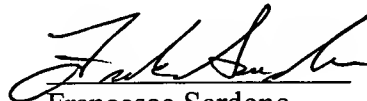
It is respectfully submitted that none of the references of record, considered individually or in any proper combination, disclose or suggest the present invention as claimed.

Should the Examiner believe that a telephone interview may facilitate resolution of any outstanding issues, the Examiner is respectfully requested to telephone Applicants' undersigned attorney at the number indicated below.

In view of the foregoing amendments and remarks, reconsideration of the application and allowance of claims 16-19, 22-33 and 36-44 is earnestly solicited.

Respectfully submitted,

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